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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,643	01/26/2001	C. Alexander Turner JR.	LEX-0122-USA	9470

24231 7590 10/22/2002

LEXICON GENETICS INCORPORATED
8800 TECHNOLOGY FOREST PLACE
THE WOODLANDS, TX 77381-1160

EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 10/22/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/770,643

Applicant(s)

TURNER ET AL

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. Formal Matters

- A. Claims 1-5 were pending in this application. In amendment A, filed 9/27/02, Applicants canceled claims 4 and 5 and added new claims 6-8. Therefore, claims 103 and 6-8 are pending and are the subject of this Office Action.
- B. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Oath/Declaration

- A. The objection to the Oath/Declaration has been withdrawn since Applicants submitted a new Declaration in which the signature of Frank Wattler matches the full printed name.

3. Title

- A. The objection to the title since Applicants have amended the title to more properly reflect the claimed subject matter.

4. Abstract

- A. The objection to the Abstract is withdrawn since numerous patents issued to the present inventors have issued with the same Abstract.

5. Claim Objections

- A. All claim objections have been withdrawn since Applicants have amended the claims to overcome these rejections.

6. Claim Rejections - 35 USC § 101

- A. Claims 1-3 remain rejected and new claim 6-8 are also rejected under 35 USC 101 for the reasons already of record on pages 4-6 of the Office Action dated 4/23/02. Applicants argue that the diagnostic assays described in the specification, which involve polymorphisms are a real-world utility and that, because of this, the present sequences must be useful. Applicants argue that the sequence of the present invention is a "neurexin-like protein" and that neurexins mediate neural processes. Applicants argue that GenBank Accession Nos. NM_130773 and AB077881 are 99% identical to that of SEQ ID NO:1 and 2 of

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the present invention and that the references cited by the Examiner do not support the lack of utility position made by the Examiner. Finally, Applicants argue that numerous issued patents do not contain examples of "real-world" utilities. These arguments have been considered, but are not deemed persuasive. First, all issued U.S. patents have a presumption of utility. Second, there are numerous known polymorphisms throughout the DNA and protein databases and that fact that the polynucleotide of the present invention may encode a single nucleotide polymorphism (SNP) is, in itself, neither substantial nor specific since any polynucleotide containing a SNP can be used for diagnostic assays. However, as discussed below and in the Office Action dated 4/23/02, without knowing the functions (i.e. utility) of the polynucleotide and protein of the present invention, one cannot assess a utility for the diagnostic assays using these molecules.

Subsequent references (GenBank NM_130773 and AB077881) by others do teach proteins which are 99% identical to that of the claimed invention. These proteins are named "Caspr" proteins and are members of the neurexin superfamily. Applicants also cite teachings by Zanazzi et al., Bellen et al., Poliak et al., Rios et al. and Spiegel et al. who teach that Caspr proteins are members of the neurexin superfamily and that the functions of these Caspr proteins are well-known. However, it is clear from the references that the neurexin superfamily comprises numerous members belonging to different subfamilies. Caspr is only a member of one of these subfamilies and members of this subfamily have their own specific and substantial functions in neuronal cells which are distinct from other members of the superfamily. While it is known, as Applicants disclose in the specification, that the superfamily of neurexins mediate neuronal processes, the specific neural processes of the proteins and genes of the present invention have not been disclosed. It would not be expected that every subfamily of the neurexin superfamily would have identical functions in the mediation of neuronal processes and that proteins in these individual subfamilies would need to be characterized in order to better understand their specific and substantial role in mediating these processes. Therefore, respectfully, simply stating that the protein of the present invention is related to neurexin and, therefore, mediates neuronal processes is neither substantial nor specific since all neurexins would mediate such general functions. Casprs, for example, appear to associate with myelinated axons and potassium channels and it is the involvement with these functions which confer a specific utility to Caspr proteins. However, Applicants have not provided any specific information regarding the specific utility of the proteins of the present invention which distinguishes them from other members of the neurexin superfamily. Therefore, one of ordinary skill in the art, only knowing that the proteins of the present invention are caspr proteins, which was disclosed subsequent to filing the present application, would still not know what the specific utility of these proteins

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was, other than the fact that they mediate neuronal processes. Therefore, one of ordinary skill in the art would not know how to use a protein, or a gene, which is only known to generally be involved in neuronal processes, along with potentially hundreds or thousands of proteins.

The references cited by the Examiner were used to show that, in absence of other supporting data, that homology alone is insufficient to determine the function of a protein. Applicants argue that the only function that the protein of the present invention has is that it “mediates neural processes.” Again, in itself, this is neither specific, nor substantial since numerous proteins, including G protein-coupled receptors, ion channels, kinases, etc. mediate neural processes. Applicants do argue that the association between neurexins and a variety of neural processes has long been recognized. However, without knowledge of specific functions of the protein of the present invention, one cannot determine that Applicants’ invention is useful.

Contrary to Applicants’ arguments, the Examiner is not implying that a real-world utility does not require further characterization, only that a patent is not a “hunting license.” If Applicants were able to establish that the protein encoded for by the polynucleotide of the present invention was a neurexin protein, then further characterization would be acceptable. However, Applicants have failed to make this association. Such uses as “for DNA chips” or for chromosome mapping is, again, neither a specific, nor substantial utility since any nucleotide sequence can be used in such an assay. While it is clear that the nucleic acid molecule of the present invention would hybridize to a chromosome, without knowing the function of the protein encoded for by this nucleic acid molecule, then simply identifying that a nucleic acid molecule localizes to a particular region of a chromosome would not provide a use for the nucleic acid molecule of the present invention.

7. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. Claims 1-3 remain rejected and new claims 6-8 are also rejected under 35 USC 112, first paragraph, for the reasons already of record on page 7 of the Office Action dated 4/23/02 as well as for the reasons given in the above rejection under 35 USC 101. Applicants argue that the claimed invention is enabled because it has utility as argued previously. Applicants’ arguments have been fully considered, but are not found to be persuasive for the reasons discussed above.

B. The potential rejection of claim 1 under 35 USC 112, first paragraph, regarding “at least 24 contiguous bases” has been withdrawn in view of Applicants’ amendment to the claim to cancel this limitation.

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8. Claim Rejections - 35 USC § 112, first paragraph – written description

A. The rejection of claim 1 under 35 USC 112, first paragraph, regarding “at least 24 contiguous bases” has been withdrawn in view of Applicants’ amendment to the claim to cancel this limitation.

9. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claim 2 under 35 USC 112, second paragraph, regarding “hybridization conditions” has been withdrawn in view of Applicants’ amendment to the claim to recite the specific hybridization conditions.

B. The rejection of claim 2 under 35 USC 112, second paragraph, regarding “complement” has been withdrawn in view of Applicants’ amendment to the claim to clarify this phrase.

10. Claim Rejections - 35 USC § 102

A. The rejection of claim 1 under 35 USC 102(b) as being anticipated by Hillier et al. regarding “at least 24 contiguous bases” has been withdrawn in view of Applicants’ amendment to the claim to cancel this limitation.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
October 09, 2002


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600